

## **REMARKS**

Claims 1-68 are pending. The Examiner withdrew claims 51-67 from consideration. Claims 1-50 and 68 are under consideration.

Applicants have amended claims 1 and 68 to recite “directly sequencing the at least one amplification product.” That amendment is supported in the specification, e.g., at page 18, paragraph 53. Applicants have amended claims 10 and 35 to recite “at least one biological source selected from . . . .” That amendment is supported by the specification, e.g., at page 7, paragraph 21. Applicants have amended claims 11, 12, 36, and 37 to recite “at least one pathogen selected from . . . .” Applicants have amended claims 13 and 38 to replace the word “and” with the word “and/or.” Applicants have amended claims 17 and 42 to recite “at least one HLA type selected from . . . .” Applicants have amended claims 18 and 43 to recite “at least one polynucleotide selected from . . . .” Applicants have amended claims 23 and 48 to recite “at least one fluorescent indicator selected from . . . .” Applicants have amended claims 25 and 50 to recite “at least one sample selected from . . . .” No new matter is added by those amendments. Those amendments simply further clarify that the claims comprise one or more of the listed items.

### **I. Rejection of Claim 49 Under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph**

The Examiner maintained the rejection of claim 49 under 35 U.S.C. § 112, second paragraph. Office Action at page 2, item 3. Specifically, the Examiner stated that “[c]laim 49 remains rejected under 35 U.S.C. § 112, second paragraph in section

4(e) since there is no specific argument regarding the rejection.” *Id.* However, Applicants believe that the Examiner has already withdrawn that rejection.

The Examiner specifically indicated in the Advisory Action mailed September 24, 2003 (“Advisory Action”), that “[t]he rejection of claim 49 under 35 U.S.C. § 112, second paragraph in section 2(c) is withdrawn.” Advisory Action at page 3, item 3. “Section 2(c)” apparently refers to section 2(c) of the Final Office Action mailed February 11, 2003 (“Final Action”). That section states that “[c]laim 49 remains rejected under 35 U.S.C. § 112, second paragraph in section 4(e).” Final Action at page 2. Thus, the Examiner withdrew that rejection in the Advisory Action. Furthermore, the Examiner indicated in the present Office Action that “[t]he rejection of claims 10, and 26-50 [including claim 49] under 35 U.S.C. 112, second paragraph is withdrawn.” Office Action at item 2. Thus, it appears that claim 49 no longer stands rejected.

If claim 49 indeed stands rejected under 35 U.S.C. § 112, second paragraph, then Applicants respond to that rejection by incorporating by reference the arguments of record in the Response After Final filed August 11, 2003, at pages 3-5 and the Amendment and Response filed February 11, 2004, at pages 15-16, section II. Therefore, Applicants respectfully request withdrawal of the rejection of claim 49 under 35 U.S.C. § 112, second paragraph, if that rejection is indeed outstanding.

## **II. Rejection of Claims 1-25 and 68 Under 35 U.S.C. § 103(a)**

The Examiner maintained the rejection of claims 1-25 and 68 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Pritham et al. (J. Clinical Ligand Assay (1998) 4:404-412), in view of Johnston-Dow et al. (U.S. Patent No. 6,103,465). Applicants respectfully traverse that rejection.

In the Amendment and Response filed February 11, 2004, at pages 18-19, Applicants argued that there was no reasonable expectation of success based on Sambrook et al., *Molecular Cloning: A Laboratory Manual* (3rd ed. 2001), page 12.106, first and second paragraphs. In response to that argument, the Examiner states that “there is [a] way to obtain a reasonable expectation of success,” allegedly through “rigorous optimization of the amplification step to suppress mispriming and *meticulous purification* to rid the PCR product of residual primer, thermostable DNA polymerase, unused dNTPs, and nonspecific reproductions of the original template.” Office Action at page 4 (emphasis added).

Without acquiescing to the Examiner’s argument and solely to expedite prosecution, amended claims 1 and 68 recite “directly sequencing the at least one amplification product . . . .” Amplification product that is directly sequenced is not subject to “meticulous purification” prior to the sequencing. See, e.g., the specification at page 18, paragraph 53; pages 18-19, paragraph 54; and page 19, paragraph 57 (discussing the sequencing of the amplification product directly from the amplification reaction without “meticulous purification” of the amplification product). Thus, the applied art would not have provided a reasonable expectation of success in “directly sequencing the at least one amplification product,” because the at least one amplification product is not subject to “meticulous purification” prior to the sequencing.

Because there would have been no reasonable expectation of success, claims 1 and 68 are patentable over Pritham in view of Johnston-Dow. Claims 2-25 ultimately depend from claim 1. Thus, those claims are also patentable over Pritham in view of

Johnston-Dow. Applicants respectfully request withdrawal of the rejection of claims 1-25 and 68 under 35 U.S.C. § 103(a).

### **III. Rejection of Claims 26-50 Under 35 U.S.C. § 103(a)**

The Examiner rejected claims 26-50 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Pritham et al. in view of Johnston-Dow et al. and in further view of Wittwer et al. (U.S. Patent No. 6,174,670). Applicants respectfully traverse that rejection.

Claim 26 recites “at least one set of reaction compositions comprising a first reaction composition and second reaction composition . . . .” The Examiner concedes that “[t]he teachings of Pritham et al. and Johnston-Dow et al. do not indicate that there are two reaction compositions involved in the methods.” Office Action at page 4. Furthermore, Wittwer discusses a method that comprises a single reaction mixture. (See col. 13, line 65, and col. 14, line 14.)

Despite those deficiencies, the Examiner attempts to support the rejection by alleging that “. . . the claim language is interpreted that the reaction can be a single reaction. . . . Therefore the teachings of Wittwer read on the limitations of [the] claims.” Office Action at page 5. That interpretation is not reasonable in view of the language of claim 26. See M.P.E.P. § 2111 at 2100-46 (8<sup>th</sup> ed. rev. 2, May 2004) (“During patent examination, the pending claims must be ‘given their broadest *reasonable* interpretation consistent with the specification.’”) (citing *In re Hyatt*, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000)) (emphasis added).

Claim 26 recites “. . . at least one set of reaction compositions comprising a first reaction composition and second reaction composition. . . .” The Examiner’s interpretation of “a *single* reaction” is inconsistent with the recitation of “first” and

“second” reaction compositions in claim 26. Claim 26 further recites that “. . . the first reaction composition comprises amplification primers specific to the at least one target polynucleotide, and the second reaction composition comprises a fluorescent indicator and amplification primers specific to the at least one target polynucleotide . . . .” Thus, the claim language distinguishes the second reaction composition from the first reaction composition by requiring a fluorescent indicator. If the first reaction composition and the second reaction composition were “a single reaction,” such a distinction would not make sense. Thus, one skilled in the art would understand that the language “at least one set of reaction compositions comprising a first reaction composition and second reaction composition” in claim 26 does not encompass a single reaction.

Furthermore, the Examiner’s interpretation of claim 26 is inconsistent with the specification. For example, the specification states that:

In certain embodiments, one does not actually sequence the amplification product from the reaction composition that includes the fluorescent indicator. In certain such embodiments, one uses at least one set of reaction compositions. The at least one set of reaction compositions comprises a first reaction composition and a second reaction composition. . . .”

Specification at page 14, paragraph 42. Thus, one skilled in the art reading claim 26 in view of the specification would understand that the “determining the sequence of the at least one amplification product of the first reaction composition” is not performed on the second reaction composition. If the first reaction composition and the second reaction composition were “a single reaction,” as the Examiner contends, then one would necessarily be sequencing amplification product from *both* the first and second reaction compositions. That interpretation is therefore inconsistent with the specification.

The Examiner's interpretation of claim 26 is neither reasonable nor consistent with the specification. Therefore, the Examiner has failed to show that the cited documents would have rendered claim 26 obvious. Claims 27-50 ultimately depend from claim 26. Thus, those claims are also patentable over the cited documents. Applicants therefore request reconsideration and withdrawal of the rejection of claims 26-50 under 35 U.S.C. § 103(a).

### **CONCLUSION**

Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the application. In the event that the Examiner does not find the claims allowable, Applicants request that the Examiner contact the undersigned at (650) 849-6778 to set up an interview.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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